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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,938	04/12/2004	Chin Ying Hsiao	09395.0001-00000	4416

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EXAMINER

MAYER, SUZANNE MARIE

ART UNIT PAPER NUMBER

1653

DATE MAILED: 03/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/822,938

Applicant(s)

HSIAO ET AL.

Examiner

Suzanne M. Mayer, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 1-40 are pending in the present application. Claims 41-53 are withdrawn from further consideration.

Election/Restrictions

2. Applicant's election with traverse of Group 1, claims 1-40 in the reply filed on 22 February 2005 is acknowledged. The traversal is on the grounds that it would not be burdensome to the Examiner to search both the method and product Groups. This is not found persuasive because of the fact that there are two patentably distinct inventions within the same application, both of which have achieved separate status in the prior art as seen by the different classification of the two Groups, which would necessarily require divergent and separate searches thus imposing an undue search burden upon the Examiner. Furthermore, the inventions are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case collagen can be made by several different methods, for example, US Patent 4,066,083.

Thus, the requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

3. The information disclosure statements (IDS) submitted on 16 July 2004 and 12 December 2004 have been received. Accordingly, the information disclosure statements have been considered by the examiner. See signed and attached PTOL-1449.

Drawings

4. The drawings are objected to because they contain figure legends and/or explanations of the figures. Only the drawings and the figures number should be present. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

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the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

5. Claims 29 and 35-40 are objected to because of the following informalities: the claim limitation of a certain volume of bacteria, e.g., 160 μ l is a 'non-limitation' in these claims as this number is completely irrelevant in the absence of a specific volume of the fermentor and culture. Rather what is the accepted value of a bacterial inoculate in the art is the recitation of 10^x cells/ml. Appropriate correction is required.
6. Claims 32-34 are objected to because of the following informalities: the recitation of X grams of salt added is a 'non-limitation' to the claim as the desired effect of the salt will be completely dependent upon the volume of culture. Rather, the accepted recitation of such a limitation should be put in salt g/L. Appropriate correction is required.
7. Claims 28-34 are objected to because of the following informalities: the word *Bacillus* is incorrectly spelled in claims 28 and 33. Appropriate correction is required.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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9. Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Bickley. Bickley teaches a process for the production of soluble collagen from a mammalian source by fermenting the collagen containing material in a fermentor with lactobacillus in an acidic medium for a time period of 48-56 hours (see p. 3, lines 45-55), followed by washing the material to remove non-soluble collagen. The collagen material was extracted by freeze drying the material, and then redissolving the collagen containing material in an acidic solution containing citric acid which was allowed to incubate for 48 hours (see p. 3, lines 59-65). The culture was then vacuum filtered. (See example 1, and Claims 1-28). Claims 10-14 are included in this rejection because as can be seen in Claim 1 of Bickley, the claim is drawn to collagen containing material which anticipates all forms and species of collagen containing material to which the instant claims are drawn.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bickley in view of Ries and further in view of Petersen et al.

The teachings of Bickley are described above in paragraph 9 of this Office Action. However, Bickley does not teach the separation methods which involve using acetic acid and pepsin to separate the non-collagen type peptides followed by filtration and then precipitation of the collagen by salt precipitation, and subsequent re-filtration of the collected and precipitated collagen.

Ries (US Patent 4,066,083) teaches the preparation and recovery of surgical collagen essentially as follows: taking collagen-containing animal tissues (see column 2, lines 15-20) and removing the water-soluble non-collagen type substances by treating the tissue with 5-10% aqueous NaCl solution (that contains NaN_3), washing the resulting fibers with 0.1-05% acetic acid, then digesting the fibers for 8-48 hours at a pH of 2.5-3.5 in a 5x volume (based on volume of fiber) with 0.1-5% 0.5M acetic acid that contains pepsin (which hydrolyzes said fibers), then precipitating the collagen from the resultant collagen suspension by the addition of aqueous NaCl, and separating the resultant collagen from the suspension by ultrafiltration, dialysis or washing in ethyl alcohol and then dissolving the collagen (if desired) in an organic water solution (see Claim 1) which results in a highly purified collagen that is suitable for surgical procedures.

Petersen et al. teach the conditioning of collagen for gelatin extraction by fermenting the collagen for 4 to 72 hours with proteinases extracted from *Bacillus subtilis* and *Bacillus licheniformis* (see claims 1-3).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the method of Bickley, however, substituting the

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micro-organism from the genus *Bacillus* because Petersen et al. clearly show that the proteinases produced from this genus are suitable for fermentation of collagen, and subsequently to purify the collagen obtained by the process of Bickley and Petersen et al. according to the teachings of Ries of a conventional purification method. Motivation to combine the teachings comes from Ries' teachings that his process is an improvement over the prior art process and that the collagen can come from any collagen-containing tissue.

Conclusion

10. No claim is allowed.

The non-patent literature cited on PTO-892 (Rama et al. and Orth et al.) are there to show the state of the prior art and that shark and chicken can be sources of collagen containing material.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Mayer, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 8.30am to 5.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

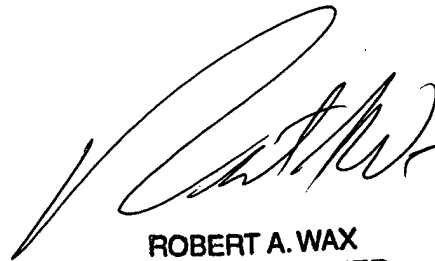
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Smm

SMM

14 March 2005



ROBERT A. WAX
PRIMARY EXAMINER

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